Intellectual property rights and health: the constraints of WHO authority and the rise of global health governance as an element of contestation

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Abstract

INTELLECTUAL PROPERTY RIGHTS AND HEALTH
The Constraints of WHO Authority and the Rise of Global Health Governance as an Element of Contestation

by Wolfgang Hein

This paper links the main issues of the project "Contested World Order" (WZB, GIGA, HSFK) to the policy field of global health: the authority of the institutional setting, and the preferences and strategies of rising powers and non-state actors (NStAs) – the assumed protagonists of recent power shifts.

The first part discusses the loss of WHO authority since the rise of Global Health Governance, and WHO's fight to reassert its position. The core of the paper deals with the conflict on intellectual property rights (IPRs) and access to medicines as a central issue in global health. Between 1995 and 2005, civil society organizations (CSOs) and some emerging powers fought successfully for improving access conditions under the TRIPS agreement (Doha Declaration). WHO's activities to regain the initiative led to the adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008) (GSPoA). Chapter 4 analyses the role of NStAs and rising powers (notably BRICS) during negotiations on implementing GSPoA. While CSOs insisted on a binding R&D treaty, BRICS countries finally agreed to more modest results. They support the welfare-orientation and the intergovernmental character of WHO but without seriously challenging basic rules in the global economy. Finally, consensus within WHO was restraint to issues which did not touch the basic IPR framework.

Keywords: WHO authority, global health governance, intellectual property rights, access to medicines, GSPoA, non–state actors, rising powers

Zusammenfassung

INTELLEKTUELLE EIGENTUMSRECHTE UND GESUNDHEIT
Autoritätsverlust der WHO und Aufstieg von Global Health Governance als Ausdruck von Contestation

von Wolfgang Hein

Der vorliegende Beitrag verbindet die Schwerpunkte des Projektes „Contested World Order" (WZB, GIGA, HSFK) mit dem Policy-Feld „Global Health". Explizit geht es um Autorität innerhalb des institutionellen Rahmens globaler Gesundheitspolitik, sowie die Präferenzen und Strategien aufstrebender Mächte und nichtstaatlicher Akteure (NStAs), welche als die Protagonisten der jüngsten globalen Machtverschiebungen angesehen werden.

Der erste Teil diskutiert den Bedeutungsverlust der WHO seit der Entwicklung von Global Health Governance und ihre Bemühungen die eigene Position zu behaupten. Der Kern des Beitrags beschäftigt sich mit dem Konflikt um geistige Eigentumsrechte (IPRs) und dem Zugang zu Medikamenten als einem zentralen Gegenstand des Bereichs Global Health. Zwischen 1995 und 2005 setzten sich zivilgesellschaftliche Organisationen (CSOs) und einige emerging powers erfolgreich für bessere Zugangsbedingungen im Rahmen des TRIPS-Abkommen (Doha Decleration) ein. Die Bemühungen der WHO, die Initiative wiederzugewinnen, führten zur Verabschiedung der Global Strategy and Plan of Public Health, Innovation and Intellectual Property in der Weltgesundheitsversammlung (2008) (GSPoA). Kapitel 4 analysiert die Rolle nichtstaatlicher Akteure und aufstrebender Mächte (insbesondere BRICS) bei den Verhandlungen der GSPoA. Während die zivilgesellschaftlichen Organisationen auf einen bindenden Vertrag zu Forschungs- und Entwicklungs bestanden, stimmten die BRICS-Staaten bescheideneren Ergebnissen zu. Sie unterstützen die Wohlfahrtsorientierung und den zwischenstaatlichen Charakter der WHO, ohne jedoch grundlegende Regeln der globalen Wirtschaft ernsthaft zu hinterfragen. Schlussendlich blieb der Konsens innerhalb der WHO auf Themen beschränkt, welche nicht in den grundlegenden Bereich der Rechte um geistiges Eigentum fielen.

Stichwörter: Autorität der WHO, Global Health Governance, intellektuelle Eigentumsrechte, Zugang zu Medikamenten, GSPoA, nicht–staatliche Akteure, Rising Powers

I. INTRODUCTION: WHO and the Transformation of Authority in a Contested World Order

According to its constitution, the World Health Organization (WHO) is "the directing and co-ordinating authority on international health work" (Chronicle 1947:3). Since the 1990s, however, the authority of WHO has been constraint by three developments: internal conflicts, unilateral international health activities by member states by-passing WHO, and the rising numbers and political influence of non-state actors in the policy field of global health. The proliferation of actors and the growing complexity of actor constellations, has led to a growing importance of what has been called Global Health Governance (GHG), a polycentric system of "collective problem-solving for improved health through the interplay of different institutional forms and actors at different levels" (Kickbusch & Cassar Szabo 2014:320f)[1].

This working paper has been written in the context of the project "Contested World Order" and is closely related to its main research questions linked to the policy field of global health. Very shortly, this concerns the authority of the institutional setting, the preferences and strategies of rising powers and non-state actors (NStAs)[2] – the protagonists of recent power shifts assumed – in basic conflicts, and the liberal content of their claims and statements[3]. Due to the proliferation of actors and institutions in global health and the growing challenge to WHO authority since the 1990s, dealing with WHO under the perspective of a contested world order implies a focus on GHG.

Taking into account the diversity of health issues, a more in-depth analysis of the role of actor positions and preferences in international health requires a focus on specific conflicts. The contest of intellectual property rights (IPRs) – strengthened in 1995 through the Agreement on

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1 After more than ten years of expanding (and mostly conceptionally rather loose) use of the GHG concept, there are a number of attempts to discuss more thoroughly the uses of the concept (See: Lee & Kamradt-Scott 2014; Kickbusch & Cassar Szabo 2014).

2 While the term "non-state actors" includes all types of actors literally meant by this term (i.e. including enterprises, religious organizations, philanthropic organizations etc.), the term "NGOs" is used here in a broad sense (including business and professional associations, but excluding enterprises), and the terms civil society organizations (CSOs) include all organizations with a strong advocacy component (including advocacy-oriented faith-based organizations).

3 For a first presentation of the research project (Stephen & Zürn 2014). The results of this project will be published in a collective volume probably in 2017.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) – by various actors demanding "universal access to essential medicines" is of particular interest regarding the rise of GHG and the authority of WHO within GHG as well as the positioning of rising powers and non-state actors in the field of global health. Furthermore, this conflict concerns a central element of contestation based on a common-goods perspective[4] against the neo-liberal[5] content of the dominant trade order.

In the second half of the 1990s two important developments linked to the profitability of pharmaceutical corporations could be observed: (1) the lack of investments into the discovery of new medicines against diseases "which primarily affect developing countries"[6] (most of the so-called tropical diseases) and (2) the impact of the TRIPS Agreement notably on the access to anti-retroviral medicines (ARVs) against HIV/AIDS. In particular, the issue of access to ARVs – people die because effective medicines are only available at prices about 100 times the production costs, and the access to generics available from the Indian pharmaceutical company CIPLA since early 2001 was prohibited in countries in which the original ARVs were patented – had lifted the discourse on the character of medicines (or better: medical innovation) as common goods to a level of public attention hardly reached by other health issues. The link to the "highest attainable standard of health" as a human right could not be denied.[7]

Design of the article and methodological considerations

In section 2, I will give a comprehensive overview on the challenges to the authority of WHO in international health since the 1990s and the attempts of the organization to reassert its key

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4 "Promoting global health" implies the provision of "global public goods" (Kickbusch 2013): This concept stresses that in addition to being non-rivalrous in consumption and non-excludable in access public goods which are available "more-or-less worldwide" become increasingly important (Kaul et al. 1999). As public goods cannot be expected to be provided in a liberal economy without any political intervention, there are two important questions to be dealt with: What has to be done (priorities) and who pays for it?

5 Seen from a perspective of competition, strictly speaking patents are not a liberal element, but a means to protect gains from innovation against what is seen as unfair practices of imitation.

6 I will use the term "developing countries" (DCs) (appearing in many quotations from UN/WHO documents) according to the UN classifications; to be more precise, I prefer the World Bank classifications (HICs: High, MICs Medium, LICs Low Income Countries) and, where appropriate refer to the BRICS and to "emerging economies" or "rising powers" as a specific cluster of countries within the MICs.

7 As a human right (General Comment No. 14; CESCR 2000) also accepted by the TRIPS council (Doha Declaration 2001) and following that by transnational pharmaceutical companies.

position. The background and main lines of the conflict on IPRs in health (1996-2005)[8] are summarized in Section 3. This section will be based on the rich literature existing on the conflict, from that the available information on the role of non-state actors and the rise of GHG on the one hand, and the "rising powers" on the other hand can be extracted [9]. During the first phase of this conflict, WHO stayed in the background. This changed after the Doha Declaration in November 2001, when WHO vehemently took up the issue of access to medicines. After various steps, which cannot be analyzed here in detail (see section 3.6), the World Health Assembly passed the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (GSPoA) in 2008. The GSPoA implied further negotiations on disputed issues (finance of the far-reaching plan and the proposal to negotiate a treaty on Research and Development in health within the WHO). Section 4 presents the empirical analysis of conflicting positions during these negotiations from 2009 to 2015, based on the positions and strategies of rising powers and of non-state actors, taken in the WHO governing institutions (World Health Assembly and the Executive Board). Section 5 will offer a conclusion interpreting the results of this analysis, coming back on the issue of authority in global health.

The processes leading to the Doha Declaration are well-researched and the literature allows well-founded statements on the issues raised here. While the positions of emerging powers will be mostly taken from the literature, NGO positions will be based on some important documents produced between 1998 and 2000. I plan to look at the following four NStAs: Doctors without Borders (Médecins Sans Frontières, MSF), Health Action International, Third World Network, ACT-UP (AIDS Coalition to Unleash Power), and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); at the BASIC countries (i.e. BRICS excluding Russia) and the positions of important Northern states. In addition, positions of other NStAs like foundations, faith-based organizations (FBOs), and other representatives of the global South will be observed in order to control the assumed specific role of NGOs and the BASIC countries.

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[8] The dating of this conflict refers to the Brazilian Patent Law of 1996 with its "local working" provision and the South African Medicines Act of 1997 as starting points and the passing of the Indian Patent Law (March 2005) and the WTO Medicines Decision (December 2005) as (interim) end-points (see sections 3.4 and 3.5).

[9] See the literature quoted in section 3; for basic information see t'Hoen 2009. The author has analysed this conflict and the impact on GHG in Hein et al. (2007) and Hein & Moon (2013).

The analysis of the implementation of the GSPoA requires some primary research. For designing an empirical study of actors' positions in conflicts around WHO, it has to be taken into account that many activities of WHO have a rather technical character. This implies a comparatively low visibility of conflicts within the organizations to the general public. Thus, in this study of WHO (in spite of CSO contributions in the debates of WHO governing institutions, "speaking at the invitation of the Chairman") it would be extremely difficult to find comparable sets of public statements by the BRICS countries and by important NGOs on crucial issues of the role of the organization in a changing world order. Therefore this analysis will basically focus on statements within the WHO governing institutions, the World Health Assembly (WHA) and the Executive Board (EB). Narrowing down our sources to WHO governing institutions should not make us forget that this inner space of conflicts is always related to an outer space of conditions, which in different ways determine the preferences and strategies of actors and the course of political conflicts. According to their position in this "outer space", the importance of getting support from WHO action (a resolution, a plan of action, material support, up to a binding treaty) considerably varies for different actors. A state that is in a position to shift considerable resources towards other support systems (networks) is less dependent from a strongly financed, independent WHO than a state with little alternative support to its health needs.

II. AUTHORITY OF WHO AND GLOBAL HEALTH GOVERNANCE

II.1 WHO: Constitutional Responsibilities, Activities and Conflicts

The antecedents of the WHO in the development of international health organizations can be traced back into the 19th century (International Sanitary Conferences) and from 1921 to 1945 to its immediate predecessor, the League of Nations Health Organization (LNHO). The hegemonic position of the US and the dominating role of the Allied Powers basically guided the establishment of the United Nations. Still, concerning the role of today's rising powers, a quote from the Chronicle of the World Health Organization (published by the WHO Interim Commission which prepared the establishment of WHO until the entry into force of the WHO constitution in 1948) should not be ignored: "To the Brazilian Delegation must be given the credit of having insisted that the concept of "health" be included in the actual Charter of the United Nations... In 1945, the Delegations of Brazil and China submitted to the San Francisco Conference a joint proposal, which was adopted, that an International Health Conference be called as a matter of urgency" (Chronicle 1947:3). The WHO constitution established the organization "as the directing and coordinating authority on international health work", but also as an agency cooperating with many different kind of actors in health (including "informed public opinion") – which could

make it today a coordinating center of Global Health Governance. Another important trait of WHO is its federal structure with six regional bureaus which are quasi-separate organizations (Hanrieder 2015); many statements in the WHO governing institutions are made in the name of WHO regions (see section 4).

The WHO belongs to the group of United Nations Specialized Agencies (UNSAs) which were originally conceived as technical organizations, in the case of WHO focusing on health expertise and the prevention of diseases, including a development component (fostering national health system in developing countries (DCs)). UNSAs are "democratically" organized, that is each member state has one vote in the governing institutions. Politically motivated conflicts, however, are not really foreseen in their constitutions; delegates are not expected to represent the interests of their countries, but (in the case of WHO) of "world health". Thus in general, decision-making in the WHO governing bodies is characterized by searching a consensus on the issues at hand as an expression of an organization conceived as "technical". Nevertheless some issues such as expanding the WHO budget to improve health care in the South (Jacobson 1973:213-215) and, since the 1990s, the issue of health and intellectual property rights have become more contentious.

WHO activities include a very broad scope of operations, such as negotiations on international conventions, a discussion forum for a broad coordination in GHG; delivery of technical support for health system development; technical coordination for specific health issues, classification of diseases, and a center of expertise on specific diseases (see the broad range of "Health Topics" on the WHO-web page (who.int). This characteristic does not support clear-cut strategies of different actors towards the WHO, as the same actors support or reject WHO activities in one or the other field. There are specific areas of more technical coordination, which are not (yet?) part of strong contestation processes, such as the Codex Alimentarius (jointly negotiated by WHO and FAO), producing "harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade" or the Special Programme for Research and Training in Tropical Diseases (TDR, together with The World Bank, UNDP, UNFPA and UNICEF).

Some important successes of WHO strengthened the authority of the organization: This concerns in particular the fight of diseases (successful eradication of small-pox and near eradication of Polio; WHO Model List of Essential Medicines) and, although already contended some years later with the onset of neoliberalism, the adoption of the concept of Primary Health Care at the Conference of Alma Ata (1978). Nevertheless, global health is characterized by a high degree of

dispersion of activities and fields of actions within and beyond WHO and by conflicts related to other global policy fields (environment, economy, trade and intellectual property rights). This latter aspect will play an important role in the case study carried out in this article.

II.2 Conflicts between (neo)liberalism and embedded liberalism: The rise of non-state and hybrid actors

The rise of neoliberalism, in the global South primarily through structural adjustment policies, had ambiguous implications for WHO. Demands from developing countries to stick to the ideas of embedded liberalism[10] gained momentum and produced a deadlock: This has resulted in WHO, like other UNSAs, becoming a specific battlefield of the Nord-South conflict in the 1960s and 1970s and sticking to DC (organized in the Group of 77) positions also after the neoliberal turn linked to the Debt Crisis of the 1980s. Large HICs (in particular the US and the UK) have contested the results of the dominant voting power of DCs in these organizations, frequently sidelining them by using other fora to solve international problems (forum shifting and the support of hybrid[11] organizations). The result was an enduring discrepancy between decision-making power and resource-based power[12]. In the 1980s and 1990s there has been an ongoing three-partite conflict on multilateralism: While developing countries continued to use their majority to push for Third Worldist declarations and for the filling of important posts with candidates from the South, powerful Northern countries, in particular the United States criticized ideological positions and a lack of effectiveness ("result-orientation") in many multilateral institutions[13]. Finally, advocacy CSOs frequently supported Third World oriented strategies in UNSAs. However, rising financial requirements and a growing tendency of the US and other HICs to support

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[10] The term „embedded liberalism" was coined by John Ruggie (1982) to characterize the post-World War II economy combining free trade with the freedom for states to enhance their provision of welfare referring to Karl Polanyi's concept of markets becoming "dis-embedded" from society during the 19th century.

[11] "Hybrid" organizations are those that combine actors linked to value systems and action logics of various sectors of society, i.e. the public sector, the private for-profit and the private not-for-profit sectors as partners at eye level.

[12] For an early analysis of this phenomenon in the case of UNESCO see William 1987.

[13] In 1999, US Congress passed the United Nations Reform Act (Helms-Biden Act), which set a number of conditions for the reform of the UN system before the US would release its total amount of arrears in payment to the UN. This also affected the WHO budget (Hein & Kickbusch 2012:215).

competing organizations to work on health problems implied a power-shift in favor of economically dominant actors.

The World Bank reinforced its role in global health through increased health-related financing in the context of structural adjustment and later poverty reduction programs, its growing conceptual influence in health systems reform (see in particular, the World Development Report 1993 "Investing in Health"), and its growing involvement in large health programs and partnerships (such as the TDR, UNAIDS, Stop TB, Roll Back Malaria) (Ruger 2005). Economic liberalization and private sector involvement was further strengthened by the adoption of the WTO agreements in 1995 (including TRIPS), which created various areas of conflict between trade and health governance, in particular related to patent rights in the field of medicines (See WHO/WTO 2002; Koivusalo 2003; and Section 3).

Thus, since the 1990s, the "directing authority" of WHO in world health has been increasingly challenged. While since then international health has gained importance in international politics (G 7/8; MDGs; UN Security Council), WHO lacked the financial foundations to come up to these challenges, being systematically starved of additional means through the zero nominal growth strategy of important members. Powerful states prefer not to work (directly) through WHO, but use various forms of (hybrid) health partnerships (see section above); financial means are attributed by philanthropic foundations (Gates Foundation etc.), hybrid funds (the Global Fund to Fight AIDS, Tuberculosis and Malaria, GFATM), individual states and (to a lesser degree) CSOs. Health CSOs, however, have been playing a stronger role in the field of advocacy and lobbying mostly opposing the impact of liberal economic rationality on health as well as organizing concrete medical support. In particular in the field of access to medicines CSOs have become the strongest supporters of what might be called informal norms of global governance (Hein & Moon 2013; section below).

The rise of non-state actors has opened up numerous options of coalition building in the growing multi-actor scene of global governance helping to overcome the North-South blockade referred to above. Non-state actors became a new element of flexibility in sectoral governance (Bartsch, Hein & Kohlmorgen 2007). The leading role of UNSAs in specific sectors has been superseded by a growing importance of increasingly complex sectoral governance structures (Breitmeier et al. 2009). Figure 1 gives an overview of the strong proliferation of actors in global health, the rise of Global Health Governance (GHG) and the loss of authority of WHO.

Figure 1: Proliferation of Actors in Global Health

Proliferation of Actors in Global Health

Period	Central Authority in Global Health	Other IGOs relevant to Global Health	NStAs (CSOs, Business Associations etc.)	Hybrid Actors	North vs. South
1950s	WHO	UNICEF	[Professional Assoc., Red Cross, FBOs, Philanthr. Org.]		North; WHO as a technical organizisation
1960s & 70s	WHO	World Bank, UNICEF	+ CSOs; TNCPs		North-South-conflict/South
1980s	WHO, World Bank	UNICEF, UNFPA, FAO	same		North-South-conflict/North
1990s	WHO, World Bank	UNICEF, FAO, UNFPA, WTO	+CSO alliances, (Gates) foundation	GPPPs; GAVI	North; health in G 7/8
Since 2000	?? (WHO?, WB?, GHG)	UNICEF, FAO, UNFPA, WTO	Further prolifer-ation on NStAs, alliances, nodal governance	+ GFATM; +ghps	CSO Alliances/ rising powers vs. North/ IPRs

Three types of actor constellations played an important role:

(a) The growing recognition of the socio-political character of health care problems (organization of health systems and physical access to health care; costs of medicines and poverty-related barriers to access) rather than being straightforward medical challenges to be overcome by the scientific progress of bio-medical and pharmaceutical research, led to an increased politicization of international health affairs.

(b) The political weight of developing countries and advocacy-oriented CSOs increased considerably and their arguments could not be dismissed as simple expressions of the North-South conflict.

(c) It was difficult to solve conflicts in global health on the level of a multilateral governmental organization with a strong voting majority (organizational power) of poor countries vs. a strong economic dominance of rich countries. The building of global health partnerships (hybrid organizations), including philanthropic organizations and nation states as sources of

international health finance outside WHO and the World Bank, played an increasing role in the development of global health governance[14].

This new architecture of global health, including the strong position of pharmaceutical corporations in a number of WHO fields of activities, explains why, on the one hand, in 2002 WTO and WHO produced a joint study on "WTO Agreements and Public Health", but on the other hand WHO was not an important actor in the first phase of the conflict on IPRs and health leading to the Doha Declaration. Health norms on which demands were based, were GHG/ human rights norms, but not norms embattled in WHO (see section 3).

II.3 WHO: Fight to Regain Authority in the Era of Global Health Governance

After the turn of the Millennium, WHO has lost most of its "directing authority" in international health, but has become one out of a growing number of GHG actors. In the field of "global health", WHO had increasingly difficulties in competing with the large and partially powerful group of non-state and hybrid GHG actors and a few powerful nation states, which frequently used opportunities to de-legitimize WHO's claim to leadership in global health (most recently with respect to its handling of the Ebola outbreak in West Africa). Nevertheless, as the only intergovernmental authority on health in the UN system[15], WHO strengthened its capacity to negotiate binding international agreements. With the negotiation of the Framework Convention on Tobacco Control (FCTC, adopted in 2003), for the first time an international treaty was negotiated under WHO auspices. The successful re-negotiation of the International Health Regulations (IHR) [16] in 2005 gave this instrument, inherited from the 19th century International Sanitary Conferences as the International Sanitary Regulations (ISR) and since then several times revised, a much broader scope of application combined with a stronger position of WHO[17].

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[14] By now there is a huge body of literature on GHG, starting with Dodgson et al. (2002). See in particular Buse et al. (2009), Moon et al. (2010; article in a four-part series on the global health system in Plos Medicine), Lee (2010), McInnes & Lee (2012), Schrecker (2012), Kickbusch & Cassar Szabo (2014).

[15] Due to its role as a financing institution and its strong research capacities, the World Bank might have a very strong position in GHG, but it lacks the formal rule-setting competencies.

[16] WHO has the competence to establish "regulations", which constitute international law if accepted by the WHA with a two thirds majority without having to be ratified by all Member States. Those not accepting certain regulations have to actively declare their withdrawal from a regulation.

[17] While the older ISR and the IHR of 1969 and 1981 only applied to outbreaks of specific diseases, the new IHR regulated interventions in all cases of "public health emergencies of international concern (PHEIC)".

After the passing of the Doha Declaration by the WTO Ministerial Conference in November 2001, WHO also succeeded in re-integrating negotiations on innovation and access to medicines into its own field of activities (see sections 3.6 and 4).

Many authors discussing GHG stressed the arising problems of coordination among the multiplicity of actors[18], and pointed to the constitutional role of the WHO as the "co-ordinating authority in international health work". While WHO supports coordination by its participation in many health partnerships, there are difficulties to create stronger institutional links with non-state actors. The very different roles of organizations representing corporate interests (and very critically observed by many WHO member states, in particular DCs) on the one hand and advocacy CSOs on the other has made it difficult to find ways to integrate non-state actors. Various concepts were proposed to find a way to institutionalize exchanges between civil society actors and WHO, in order to further develop the coordination role of WHO in GHG. The idea of a regular World Health Forum was proposed by the WHO secretariat in July 2011, but the first forum scheduled for Geneva in November 2012, was cancelled as DCs and some CSOs were afraid that such a forum might be used by pharmaceutical corporations to strengthen their position in WHO discourses. The WHA discussion ended-up in an attempt to develop a comprehensive "framework of engagement with non-state actors" to be passed at WHA 2016 (WHO 2015). This framework basically consists in determining the rights of different types of NStAs at the WHO governing institutions, the engagement of WHO in activities with NStAs and a set of criteria how to assess their impact on WHO work (participation, resources, advocacy, technical collaboration).

The new WHO Reform (2010f.) constitutes another element of the WHO strategy to regain authority. One of the most central issues concerns the financial basis of the WHO. As mentioned above, since the 1990s the US and other HICs insisted in a freeze on increases in assessed contributions. This has made WHO dependent on voluntary contributions (now at about 80% of the total budget; only 52% were received from Member States, the rest from private sponsors), which frequently are attached to specific projects. Thus the providers of voluntary resources have an unconstitutionally strong impact on WHO politics because the largest part of

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They greatly extended the authority of WHO to collect and information on disease outbreaks and, finally, gave the WHO Director General the authority to declare a PHEIC.

[18] See e.g. various contributions in the Fall 2010 issue of the Journal on Law, Medicine and Ethics (vol. 38:3) on Global Health Governance.

contributions is not controlled by the budgetary negotiations at WHA. In 2010 member states were invited to comment on a list of issues which also include priorities of WHO work and questions of governance. There were no comments from the US, India and South Africa. China suggested to explore "innovative financing channels" and to "consider an appropriate portion of donations from companies and NGOs"[19]. Finally, in 2013 there was a rather broad consensus on a new model, which inverts the normal budgeting process without increasing assessed contributions. The new *Programme Budget* (PB) will not be decided on the basis of expected income, but financing is explicitly sought for a PB draft, agreed on in a preceding strategic planning and preparation phase and decided by WHO governing institutions. Only Brazil voiced a certain concern about the continuing high dependence of the WHO on voluntary contribution. All four CSO speakers, however, had serious reservations about the new financing model, two of them explicitly demanding "a substantial increase in assessed contributions" (Medicus Mundi International) or a need for an "adequate regular budget support" (MSF International).

Member states are reluctant to strengthen the financial basis of the organization in a measure which would allow WHO to really perform a coordination role. While high-income countries have used their economic strength to support global health activities sidelining WHO, CSOs and low-income countries, mostly, but not consistently supported by the BRICS, expressed their interest in strengthening WHO as the leading international public health organization. There remains, however, a fundamental distrust concerning the impact of transnational pharmaceutical corporations (TNPCs). This is not only related to the different logics of action of profit-oriented private companies compared to public-health-oriented state actors and advocacy CSOs, but also to the huge differences in economic capacity between pharmaceutical corporations and the national health sector in LICs: While in 2009, TNPCs disposed of an estimated global market of 856 Billion US$ (Frenk & Moon 2013:938), i.e. US$ 125.34 per capita of the world population, low income countries just spent US$ 25 per person on all aspects of healthcare[20]. Thus a growth-oriented pharmaceutical industry must have different priorities than serving people in low-income countries, while high-income countries with an average health-spending of more than US$ 4,600 (National Research Council 2012) offer significant markets as well as the economic leeway to shape their health systems in spite of high prices of medicines. The following sections

[19] See http://www.who.int/dg/future_financing/china_20100723.pdf?ua=1, 06/06/2016.

[20] See: National Research Council (NRC) 2012, chapter 6 (Health Financing in sub-Saharan Africa).

of this article will analyze the "original" access-to-medicines conflict (1996-2005) being fought in the expanding field of GHG, and the following conflicts around the implementation of the GSPoA, adopted by WHO in 2008. Both conflicts show the institutional changes in a field of arising global governance emerging from the crisis of the post-WW2 world order.

III. ACCESS TO MEDICINES, TRIPS AND GLOBAL HEALTH GOVERNANCE

III.1 WHO and Medicines until the 1990s

Delivery of medical supplies (except for training and demonstration) had been excluded from WHO work since its foundation, due to insistence by the U.S. (Jacobson 1973:187). Prices and access to medicines began to play an important role in the work of WHO in the 1970s, when the WHO Model List of Essential Medicines was established, which primarily aimed at helping DCs to buy cheap and effective drugs against diseases prevalent there, without being dependent on advertisements of pharmaceutical corporations. In general, however, until the 1990s patents had not played an important role concerning medicines against "diseases of the poor" (such as gastrointestinal infections; tropical infectious diseases, etc.) due to the lack of new medicines against these diseases. Most of those medicines were no longer under patent protection[21]. On the whole, however, innovation in the field of medicines was not a central issue in the work of WHO until the 1980s, which has been documented in four volumes on "WHO history" (WHO 1968a, 1968b, 2008, 2011), but work on the quality assurance of medicines had been extended in the 1980s and 1990s (WHO 1997, Introduction). In 2001, WHO established a system of prequalification of medicines as a service to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria, tuberculosis and reproductive health (supported by UNAIDS, UNICEF, UNFPA and the World Bank; http://apps.who.int/prequal/). The primary goal is to support countries with limited access to quality medicines and to help agencies and organizations involved in bulk purchasing of medicines.

[21] At a conference on "Increasing Access to Essential Drugs" in 1999, David Earnshaw of SmithKlineBeecham insisted: "It is difficult to understand why patents are seen as such a problem. In reality, about ten of the 300 or so medicines on the WHO Model List of Essential Drugs [at that time ARVs were still not in this list, W.H.] are still under patent and of these, all but one will be off patent within the next three years." (WHO 1999: 220)

III.2 TRIPS Agreement and Access to Medicines: Basis Problems and Developments

Since the second half of the 1990s, the issue of *access to medicine* (in the first years primarily related to access to HIV/AIDS medicines) has been one of the most important and contentious issues in Global Health Governance. The "Access to Medicines Issue" constitutes a fundamental conflict between human rights norms (health) and international economic norms (IPRs). The prices of anti-retroviral medicines (ARVs) against HIV/AIDS which entered the market in the late 1980s constituted the starting point of the access conflict. Since 1996, drug combinations were available (and began to be widely used in the HICs) which transformed HIV/AIDS into a chronic disease but cost about US$ 8,000 – 10,000 a year for the drugs alone. This was not due to the production costs of the drugs but to TNPCs exploiting patent rights, now internationalized due to the WTO Agreement on Trade-related Intellectual Property Rights (TRIPS). By requiring all member states to provide a minimum level of IP protection domestically, TRIPS was intended to harmonize IP policies across HICs and DCs with rather high minimum standards (e.g. 20-year patent terms, rules on copyrights, trademarks, etc., and on IP enforcement). Meanwhile, in certain countries companies could (legally, because of TRIPS transitional provisions) produce the same drugs as generics for a fraction of these costs, India being the main producer of such generics.

At the outset of this conflict TRIPS was strong on implementing IPR norms (because of the enforcement of the WTO dispute settlement process), while health interests had been comparatively weak. In a joint study by WHO and the WTO Secretariat (2002), WHO referred to a resolution adopted by the World Health Assembly in May 2001 (when pressure on WTO/TRIPS has been growing, but still before the Doha Declaration), which noted that "the impact of international trade agreements on access to, or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated." (WHO/WTO 2002: 107).

Thus, the access conflict confronts two fields of norms, which had developed mostly independent of each other: public health on the one hand and intellectual property rights and innovation on the other. This translates into a dispute on priorities between the fundamental aims of WTO and WHO, while both accept in principle the goal of the other (WTO Preamble: trade has a positive impact on welfare; WHO Medicines Department: IPRs are an important incentive to innovation). However, we face a more complex situation, when we analyze positions, preferences and strategies by specific groups of actors such as non-state actors and rising powers. Among both types of actors we find diverging positions between different interests and motivations

(advocative CSOs; business associations; different groups of emerging powers) in WTO and in WHO, which will have to be taken into account in the following sections.

III.3 Non-State Actors in the access conflict

The engagement of NStAs in global health is not really new. The UN Charter (chapter 10, article 71) provides for a consultative role for organizations "which are neither governments nor member states". Since its foundation, WHO has a register of "Non-governmental organizations in official relations[22] with WHO", the number of which has been continuously increasing from about 10 in 1948 to close to 200 in the end-1990s (in 2015: 202) (http://www.who.int/civilsociety/en/ngos_since_1948.gif). While the terms NGOs and CSOs mostly refer to organizations in the fields of advocacy and/or philanthropy/solidarity-oriented cooperation, the concept NStAs, strictly speaking, includes all social actors beyond the state and thus the full range of interests within society. The classification used in the WHO draft on "engagement with non-state actors" (WHO 2015) points to their great diversity:

- Non-governmental organizations (including grassroots community organizations, civil society groups and networks, faith-based organizations, professional groups, disease-specific groups, and patient groups),
- Private sector entities (commercial enterprises and international business associations),
- Philanthropic foundations,
- Academic institutions.

The political role of advocacy CSOs grew considerably during the 1990s. Their strength lies in their capacity to mobilize public pressure towards their specific goals. The first very successful international CSO campaign in health was a protest against the aggressive marketing of baby food substituting for breastfeeding, starting in the early 1970s in particular directed against Nestlé. The campaign supported (and still supports) the promotion of breastfeeding by WHO and UNICEF which led to the adoption of the International Code on the Marketing of Breast Milk Substitutes in 1981. CSO advocacy on access-related issues started in the early 1980s (HAI 2006),

[22] The status of non-state actors (usually called NGOs encompassing all four types of NStAs classified below excluding commercial enterprises) in "official relations" is used throughout the UN system (UN Charter, chapter°10, article 71). The application for being in "official relations" with WHO is rather complicated, but this status includes the right to make statements at WHA and WB. (WHO 2002)

but concentrated until the mid-1990s on negative side-effects of specific pharmaceuticals (Chetley 1993).

CSO demands for improved access to ARVs started in the mid-1990s when effective drug combinations became available more or less at the same time when the TRIPS Agreement entered into force. In 1996 Health Action International (HAI) together with the BUKO Pharma-Kampagne organized the first conference on public health and TRIPS (Stoeva 2010: 111; HAI 2006) and the US-based NGO ACT-UP (AIDS Coalition to Unleash Power) stepped up its actions coining the slogan at the Vancouver International AIDS Conference, addressed at TNPCs: "Greed Kills-Access for All". This phase culminated in the so-called Amsterdam Statement promoted by three CSOs (Health Action International (HAI), Médecins Sans Frontières (MSF) and the Consumer Project on Technology (CPT, later Knowledge Ecology International) on the eve of the WTO Ministerial Conference in Seattle (1999). The conference in Amsterdam and the Amsterdam Statement can be seen as the starting-point of the Access to Medicines Campaign, led by MSF, which had gained international prestige (and financial resources) by winning the Nobel Peace Prize in the same year. Furthermore developments in three rising powers were widely recognized by CSOs as landmarks within the access conflict: the Brazilian and South African trade conflicts to secure cheaper access to ARVs, and the production of generic ARVs by the Indian pharma industry (See Section 3.4). A number of central demands can be extracted from the following main statements of CSOs:

(1) The "Consensus Statement on the Pricing of Abacavir and Efavirenz[23]", published by ACT-UP in September 1998, endorsed by 101 organizations from all over the world and 182 individual professionals from the field of HIV/AIDS research and treatment. (www.actupny.org/alert/Dupont/Alert.html)
(2) The statement by Health Action International at the Ad hoc Working Group on the Revised Drug Strategy at WHO in October 1998 (WHO 1999).
(3) The so-called Amsterdam Statement, referred to above (published in: WHO 1999:223-224), by HAI, MSF and CPTech.

[23] Efavirenz (marketed as "Sustiva") and Abacavir (marketed as "Ziagen") are two ARVs approved by the US Food and Drug Administration in 1998 which play an important role in drug combinations against HIV/AIDS.

(4) The "Global Manifesto to Save 34 Million Lives" formulated by the South African Treatment Action Campaign (TAC) (see Section 3.4) and the mainly US-based Health GAP (Global Access Project) Coalition at the International AIDS Conference in Durban 2000), supported by many other CSOs (TAC/Health GAP coalition 2001).

a. Prices should not be set according to profit interests of TNPCs, but related to production costs and needs (lower the daily costs of long-term treatment). Public health interests ought to have priority over patents and commercial interests [24].

b. High costs of HIV/AIDS treatment puts high pressures on health budgets and reduces the quality of care in other areas[25].

c. Call upon high-income countries to increase aid for HIV/AIDS treatment[26].

d. Because of limited effective (solvent) demand from health systems in poor countries, there have been little research & development efforts related to diseases which primarily occur in poor countries and thus cannot be expected to yield average returns on R&D investments ("neglected diseases"). Research ought to take into account needs in DCs[27].

e. TRIPS flexibilities (compulsory licenses, parallel importing, non-commercial/ government use of patents, restrictions of data exclusivity[28]) have to be used safely without the risk of costly trade conflicts[29].

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[24] This argument is present in all four texts. While statement (1) accepts innovation costs ("The long-term survival afforded by the present generation of therapies makes it possible for manufacturers to set lower, or at least stable prices, and still have adequate incentive to reinvest in continued development of HIV/AIDS drugs."), later "de-linking" of prices of medicines from costs of research (see (e)) have become the broadly accepted demand.

[25] In statement (1) this is directly related to the financial restraints of AIDS Drug Assistance Programs in the US, but the situation certainly is much worse in developing countries.

[26] This is particularly stressed in the Global Manifesto of 2000 (statement 4), which addresses different demands to various groups of actors (here: "To the Governments of the USA and European Union").

[27] This issue of "neglected diseases" or "market failure to develop and market affordable drugs for diseases most prevalent in poorer regions" is taken up in statements 2 and 3.

[28] "(Test) data exclusivity refers to protection of clinical test data required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications."(https://en.wikipedia.org/wiki/Test_data_exclusivity).

[29] The Amsterdam Statement calls upon the WTO to establish a Standing Working Group on Access to Medicines. Statements (2) to (4) all demand the secure use of TRIPS flexibilities in order to ensure the protection and promotion of public health. This implies renouncing "trade sanctions and other punitive measures exercising the right to protect the health and well-being of their populations" (Statement 4) by making use of these flexibilities, and a restriction of these flexibilities through bi- and multilateral

f. De-linking prices of medicines from costs of research[30].

The basic point of reference is "public health" vs. profit interests of TNPCs, while explicit references to human rights in the 1990s only played a marginal role. However, documents from the UN Human Rights system, such as the role of health in the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights (ESCR) and in particular the General Comment 14 ("The right to the highest attainable standard of health") issued by the UN Committee on ESCR in 2000, gained importance after the turn of the Millennium.

Getting concise evidence on the impact of advocacy CSOs on political processes is difficult. Concerning the access conflict, we can observe (a) a strong political presence of CSOs in through an increasing media presence[31], and (b) that after a period of more or less five years from the end-1990s to about 2005 many of the claims made by them had been accepted by actors originally strictly defending IPRs (most HICs, TNPCs and industry associations; see below: paragraph on TNPCs and Section 3.5). However, what had been the relative impact of advocacy CSOs on the one hand and LICs and MICs on the other, and how did CSOs and state actors interact? (See: Drezner 2005). Various publications stress the impact of the Access Campaign on global public opinion, scandalizing the lack of access of people living with HIV/AIDS to existing life-saving medicines (Harris & Siplon 2001; Sell & Prakash 2004; Fischer-Lescano 2005; Tarrow 2005; Barmania & Lister 2013; Hein & Moon 2013). In spite of the support for IPRs in US foreign economic politics, opinion polls in the US indicate a strong support for government policies to

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trade agreements.

30 Since about 2000, this has been broadly accepted as a more general demand to overcome the argument that high prices are necessary to finance innovation. Nevertheless, conflicts remain on the concrete policies and their scope to support a "de-linking" process (donation programs for poor countries vs. a "medicines R&D treaty" (see section 4 of this paper).

31 Joshua W. Busby (2006:28) reports that the number of articles in major newspapers related to HIV/AIDS and Africa increased from 500 in 1997 to 1000 in 2000. The dissertation by Thomas Owen (2012) examines the press coverage of the access dispute in prominent US, UK and South African news media. He analyses how external events (such as the South African Medicines Act and the ensuing court case initiated by the pharmaceutical industry; the appearance of generic versions of ARVs; and large demonstrations for access to ARVs) were reflected in media coverage and transformed the discourse between 1997 and 2003: "...the factors of IPRs and generic medicines became central concerns in the media coverage" (ibid.: 278). See also Owen (2013).

improve access to affordable drugs[32]. Representatives of interest groups interviewed in Geneva talked (or complained) about the pressure felt from the media (Hein 2007: 50).

On the other end of the political spectrum of NStAs, TNPCs and their chief industry association IFPMA strongly defended patents and the TRIPS agreement as the fundamental incentives for innovation. However, they could not object to the general goal of facilitating access to medicines for those in need. The statement by David Earnshaw (1999) of SmithKline Beecham at the Amsterdam Conference, includes the basic arguments, regularly repeated by TNPC. TRIPS flexibilities (compulsory licenses, parallel trade, etc.) are accepted in principle, but ought to be used as absolute exceptions and not as a means to solve the problem of access. Earnshaw talks of "lack of health care infrastructure and global inequality" as the "real barriers to access" (ibid., 221) and praises important drug donation programs as well as the possibility of differentiated prices (if DCs outlaw parallel trade) and the cooperation within PPPs to meet the needs of poor countries. He also stressed the growing importance of corporate social responsibility (see also: Hein 2015:219f). The "Big Pharma discourse" (see the summary in Owen 2012:207-222, also Association of the British Pharmaceutical Industry (ABPI 2007)) also stresses corruption in DCs, the falsification of medicines (blurring the difference to the production of generic versions) and includes a campaign against high taxes on essential medicines in many DCs (Interview by the author with Eric Noehrenberg, IFPMA, on 1 Dec. 2005). Later on, however, the Doha Declaration and the so-called "Medicines Decision" (§ 6) (See Section 3.5) are accepted by the IFPMA (IFPMA News Releases, 12 Dec. 2005), but TNPCs have always insisted on a narrow interpretation of all exceptions to IPRs.

III.4 Rising Powers in the access conflict

While advocacy CSOs clearly support health goals (adjustment of medical innovation and of prices of medicines to health needs), TNPCs fight for upholding intellectual property rights as the central incentive to innovation. There is an old discourse about technological leaders favoring strong IPRs, while technological late-comers object to that, as for them strong IPRs would preclude the chances to catch up through re-engineering imported innovative products[33].

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[32] See data of a Harris Poll conducted in July 2004 for the Wall Street Journal's Health Industry Edition (www.harrisinteractive.com/news/printerfriend/index.asp?NewsID=831 , (5/18/2006)).

[33] See recently the edited volume Okediji & Bagley (2014) with a number of important articles on patent

Developing countries, in particular India, only reluctantly agreed to the US demand of integrating an agreement on IPRs into the WTO negotiations (UNCTAD/ICTS 2005:6). But at the end interests to support own innovative industries and to take advantage of trade liberalization in other sectors prevailed. Since then, can we observe any impact of the strengthened position of the rising powers in international affairs, in particular the BRICS countries, on IPR matters concerning access to medicines?

The BRICS as an organized country grouping (first summit without South Africa in 2009) did not exist during the access conflict (as dated here). While Russia had not been a WTO member until 2012 and China accessed WTO in 2002 with no clearly defined policy on the generic production of and access to ARVs (Grace 2005), the three other BRICS members played a decisive role in the development of this conflict – due to their legal and industrial activities challenging positions of the TNPCs and the HICs supporting them.

Brazil[34] was the first DC to provide widespread access to HIV/AIDS medicines. In 1990 the health ministry decided to provide HIV medicines to all patients in need, made financially possible through the local production of generic AZT[35]. In 1996 Brazil passed a new patent law, supposedly conforming with TRIPS rules, but including a "local working" clause, that is TNPCs had to produce drugs locally within three years of patent approval – if not, the government was authorized to issue a compulsory license. In the same year, a law was passed which guaranteed "all medication necessary for treatment", including new medicines for combination therapies. By combining price negotiations with TNPCs (supported by the threat to issue compulsory licenses) with demands for local production, Brazil succeeded to provide the necessary medicines. The government also succeeded in getting the US to pull back a complaint at WTO (on the local working requirement) by filing a counter-complaint. Brazilian diplomacy played an important role in forging an alliance with about 50 DCs, which led to the Doha Declaration in November 2001[36]. Brazil also initiated a resolution in the UN Commission on Human Rights on "Access to

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law in a historical perspective.

[34] This paragraph is based on Calcagnotto 2007, Wogart et al. 2009, and Hein &-Moon (2013: 68-71).

[35] AZT (Azidothymidine, marketed as Zidovudine and Retrovir) was the first U.S. government-approved treatment for HIV (in 1987) (https://en.wikipedia.org/wiki/Zidovudine).

[36] This started with a strong Brazilian presence at the Durban International AIDS Conference in June 2000, where Brazil in a meeting with the health ministers of Nigeria, India, China and Russia organized by UNAIDS offered a free transfer of technology to requesting countries for the local production of generic

Medication in the Context of Pandemics such as HIV/AIDS" (Hein/Moon 2013:71). Besides these achievements in the international arena, Brazil was successful in containing the spread of HIV/AIDS on the national level: in 2006, the number of HIV-infected people (620,000, UNAIDS 2006:321) was below a PAHO estimate for 1992 (770,000) (PAHO 1992:1-8).

South Africa[37] constitutes a strange case, as on the one hand ANC governments initially refused to provide anti-retroviral treatment in public hospitals[38], but on the other hand incurred legal conflicts with the pharmaceutical industry between 1997 and 2001, related to the 1997 Medicines and Related Substances Control Amendment Act, which gave the Minister of Health the power to authorize compulsory licensing and parallel importation of patented medicines. The Pharmaceutical Manufacturers Association (PMA) of South Africa in 1998 and again in 2001 sued the government before South Africa's High Court for violating their property rights (based on TRIPS), supported by the US government, which threatened to impose trade restrictions on the country (Lanoszka 2003:191-192). In both cases, however, pressure/demonstrations etc. by South African and international CSOs convinced the PMA to withdraw the lawsuits. In particular in 2001 mobilization around the court case found a great echo in the international press (See Owen 2012). Finally, in a further court case, the High Court forced the government to finance ARV treatment, which was another success for CSOs.

India[39] benefitted from the transition rules of the TRIPS Agreement, which allowed India to postpone the passing of a new patent law until 2005, having already a system of patent protection in place (TRIPS, Art. 65.4). India had introduced a Patents Act in 1972, which protected only production *processes* but not *products* as such. Based on that (and a rather developed industrial capacity in general), India had developed a high standard generic production[40], and had become one of the leading global producers of generics. By 2008, India has supplied 86% (by

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drugs and a diplomatic initiative to put the access to ARVs on the agenda of international negotiations (Calcagnotto 2007:188f., See also Section 3.5).

37 This paragraph is based on von Soest & Weinel 2007 and Hein & Moon 2013:71-75.

38 The main arguments were related to the high costs of treatment, but at least by some politicians supported by the negation of the link between HIV and AIDS. Here, this conflict cannot be dealt with in detail.

39 The paragraph on India is based on Hein & Moon 2013:115-119. See also Chaudhuri 2010.

40 The quality of many Indian generics has been approved by the WHO Prequalification Programme; also various international health partnerships in the field of HIV/AIDS accepted the use of generics in programs they financed.

volume) of ARV drugs in DCs (Waning et al. 2010). For continuing this role of providing cheap generics to DCs (but increasingly also to HICs, with has led to a growing importance of this sector for the Indian economy), the passing and implementation of a well-adapted new Indian Patent Law in 2005 had been important. CSO groups in India, but also from many other countries exerted pressure on the Indian Prime Minister and Parliament to take into account the widespread international reliance on Indian generic medicines (Health Gap et al. 2004). In fact the patent law passed on March 23, 2005 allowed continued production of generics that were already on the market, included strong rules on patentability and implemented a relatively simple system for compulsory licensing. With respect to existing generic ARVs, TNPCs in general did not challenge the new law, but immediately conflicts arose regarding new medicines on non-communicable diseases, in particular cancer. This relates to an issue of interpreting TRIPS flexibilities (primarily the use of compulsory licensing) and thus also of the Doha Declaration, i.e. whether those are basically applicable to HIV/AIDS, Malaria, Tuberculosis and other so-called "diseases of the poor" or to health emergencies of any kind and the respective medicines (See Section 3.5).

While Brazil, South Africa, and India, well aware of the broad interest in many sectors of their economy in WTO membership[41], never generally questioned the rationale of IPRs, but strongly defended a secure use of TRIPS flexibilities, among CSOs the idea of a medical R&D Treaty substituting TRIPS regulation with respect to medicines won increasing support.[42]

III.5 The Doha Declaration and the WTO Medicines Decision

The pressure from CSOs and DCs (with a strong role of Brazil in coordination with other emerging powers), as summarized in sections 3.3 and 3.4, and the growing concerns in the US and other HICs about the AIDS crisis resulted in November 2001 in the so-called Doha Declaration

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[41] The interest in trade liberalization is also documented by various bilateral trade agreements which they negotiated (even including so-called TRIPS+ provisions in conflict with their insistence on TRIPS flexibilities in the medicines field), but which cannot be discussed here in more detail (See Hein & Moon 2013:64-66).

[42] The idea of a medical R&D Treaty was initially proposed by James Love (cptech) in December 3, 2002 in a. presentation given at The Drugs for Neglected Diseases (DND) Working Group, in Rio de Janeiro, Brazil. It was presented to WHO in 2005 (http://www.cptech.org/workingdrafts/rndtreaty4.pdf (31-05-2016) and promoted in many publications (see cpTech, Trade Framework for Funding Research and Development, http://www.cptech.org/ip/health/rndtf/ (31-05-2016).

on the TRIPS Agreement and Public Health at the WTO Ministerial in Doha. It certainly helped that many member states from the global North had an interest to win support for the start of the so-called Doha Round of trade negotiations (t'Hoen 2009:29f). The Doha Declaration strongly reinforced TRIPS *flexibilities*, in particular the right of governments to issue compulsory licenses, affirming "that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular to promote access to medicines for all" (§ 4). Though the Doha Declaration was broadly recognized as a landmark compromise in the access conflict, the extent to which compulsory licenses could be used remained contested: Paragraph 1 reads "We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" (similar §5c). The text of the Declaration clearly says that the diseases mentioned are examples that do not limit the scope to a fixed set of diseases, but it is frequently misinterpreted in such a way that corresponds to a more restricted understanding of TRIPS flexibilities (t'Hoen 2009:32).

This conflict played a central role in the following negotiations demanded by Paragraph 6 of the Declaration on the conditions for a state without the necessary production capacities to issue a compulsory license for production of a medicine in another country. In these negotiations we can observe a strong coalition between CSOs and DCs concerning parts of the three main issues (Abbott 2005; t'Hoen 2009:35-38, 131-136):

(a) the scope of diseases, as referred to in the last paragraph, where many statements by CSOs[43] and a so-called "Nonpaper on substantive and procedural elements" presented to the TRIPS Council by South Africa[44] warned against narrowing down the scope of applying TRIPS flexibilities.

(b) the way of linking the required §-6-decision to the TRIPS Agreement, either through modifications to Article 30 (concerning the exclusive rights of patent owners) or to Article 31 (in

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[43] See the list presented by Abbott (2005) in Fn. 80, which includes statements by the most important CSOs in the access conflict (MSF, Oxfam, Health Action International, Third World Network, CPTech).

[44] Sources of the nonpaper: Inside U.S. Trade on October 25, 2002; WTO Ref. Job(02)/156 (Nov. 4, 2002) Members speaking in support included Argentina, Bolivia, Brazil, Botswana, Cuba, Egypt, India, Indonesia, Kenya, Malaysia, Pakistan, Peru, the Philippines, Sri Lanka, and Thailand, but this list does not imply that only the listed members supported the positions in the paper. (Abbott 2005, Fn. 84).

particular waving the condition that medicines produced under compulsory licenses ought to be primarily directed at national markets). Against opposition from CSOs and most DCs[45], here the US position (to modify §31) prevailed, though it implied more complicated procedures.

(c) establishing criteria for the eligibility of countries as importers and exporters in the system proved complicated, but were not contested along HIC/DC lines and also received less attention by CSOs. While LICs automatically qualify as "eligible importing members", in other cases, eligibility implies a declaration that a country has insufficient manufacturing capacity for the "product(s) in question" according to criteria set in an annex to the decision, again a somewhat laborious process (Abbott 2005:334-338).

This finally resulted in the *WTO Medicines Decision* by the WTO General Council on August 30, 2003 and a subsequent amendment of the TRIPS Agreement at the Hong Kong ministerial conference in December 2005. This can be seen as the final step of the "access conflict", in as far as the authorized interpretation of TRIPS is concerned. The outcome of these negotiations has been considered as successful in as far as a restriction on specific diseases and specific groups of DC was prevented, but the burdensome processes prescribed has been severely criticized by CSOs and many developing countries and worked as a disincentive to make use of the mechanism (t'Hoen 2009:36f).

Thus, strong international pressure (based on normative or discursive power and supported by technological capacities in the production and management of generics) modified the balance of power between international trade and health norms. This was to a large extent due to the growing impact of CSO activities and to the leadership taken over by Brazil, and to a lesser degree, India and South Africa in international negotiations. In spite of this –from the perspective of health– generally favorable results, the access conflict is not really over. In particular, investments in the field of diseases with a high incidence in poor and rich countries resulted in drugs sold at high prices under patent protection (new generations of ARVs, the anti-cancer drug Glivec from Novartis, the Hepatitis C drug Sovaldi from Gilead and others), which makes these medicines inaccessible to poor populations without price concessions by the patent

[45] See Abbott (2005:338-343), Fn. 148, and the "Joint letter from Consumer Project on Technology, Essential Action, Medicines Sans Frontieres, Oxfam International, Health GAP Coalition, and the Third World Network to the World Trade Organization's TRIPS Council" of 28 January 2002 (http://www.cptech.org/ip/health/art30exports.html; 01/06/2016).

holders. TRIPS flexibilities were strengthened by the Doha Declaration, but a margin of interpretation was left.

III.6 WHO coming back in

After WHO had hesitated to take a clear position before the passing of the Doha Declaration, the organization now fully endorsed the use of generics in the fight against HIV/AIDS. ARVs were added to the List of Essential Medicines in April 2002 and together with UNAIDS the so-called 3 by 5 initiative was launched on World AIDS Day (1st December) 2003: While at the end of 2002 the number of infected people on ARV therapy in low- and middle income countries stood at 240.000, the goal was set to reach 3 million by 2005[46]. The initiative was supported by all major funders of AIDS treatment in DCs (the GFATM, the World Bank and important national donors as reported by WHO after a coordination meeting in 2004[47]), which helped to boost WHO's authority in the fight against HIV/AIDS.

In 2004 WHO established the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), which in its final report (CIPIH/WHO 2006) stressed the need to support the development of research and the production of medicines on "diseases which disproportionally affect developing countries", the so-called "neglected diseases"[48]. CIPIH provided the connecting link between the "access conflict" and the GSPoA. Due to the determination of many WHO member states to see a strong follow-up process to the CIPIH report, an *Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)* was established by the World Health Assembly in 2006, which negotiated the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoA),* adopted by the WHA in May 2008 (See: WHA 61.21; PHM 2011:Part D1; Hein & Moon 2013:143-158).

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[46] Though at the end of 2005 only to 1.3 million were on ARV therapy, this result could still be seen as a success.

[47] See the WHO page on "The 3 by 5 Initiative", http://www.who.int/3by5/newsitem9/en/ (02/06/2016).

[48] In the following the term "neglected diseases" is frequently used as a short term for the official formulation "diseases which disproportionally affect developing countries", though in the literature it is not always exactly used in the same way.

IV. THE GSPoA AND CONFLICTS ON ITS IMPLEMENTATION

IV.1 Main features of the GSPoA

The GSPoA constitutes an instrument to reassert a "directing and coordinating" role of WHO in the field of innovation and intellectual property, including the issue of access to medicines. It can be seen at least as a partial forum shift for pharmaceutical policy as an issue of public health away from WTO towards WHO. The main aim of this strategy is to "(...) provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases which disproportionately affect developing countries." (GSPoA, Art. 13) The GSPoA established a new global framework for financing and managing health R&D, including proposals for a prize fund to support R&D investments[49], support for public-private development partnerships for medicines as well as the establishment of patent pools concentrating on the needs of developing countries in access to medicines. Though the GSPoA itself is not a binding agreement, it constitutes an authoritative decision by WHA, which includes the mandate for further negotiations on the two most important open issues: the R&D treaty to develop a binding framework for delinking the prices of medicines from the costs of R&D (see above, fn 42) and an agreement on a system of financing the plan.

While the access conflict was basically fought in the broader GHG context with a focus on WTO/TRIPS, negotiations on the GSPoA follow-up focus on the capacity of WHO to negotiate an internationally binding agreement, which is closely related to find alternative ways *to incentivize R&D* according to health needs, and to *raise substantial financial means* to support essential health research in developing countries. This again implies a severe challenge to the weak financial basis of WHO. Therefore, proposals were presented and contested within WHO governing institutions and issue-related working groups, which allowed to analyze statements of different groups of actors by scrutinizing the respective documents and to pursue the question whether WHO has been successful at regaining authority in a contested world order.

[49] A "prize fund" intends to replace the need for a patent-based monopoly by providing a risk-adjusted reward that would allow investors to recoup their R&D costs and earn a fair profit; at the same time, the end product could immediately be produced by competing manufacturers so that price would approach the cost of production in a competitive market. (Hein & Moon 2013:153). So far there have been limited tests of such a model, among others by the Gates Foundation.

IV.2 Implementing the GSPoA

After its adoption by the WHA 2008, the Executive Board discussed the completed plan of action in January 2009, and estimated the costs of its implementation at about US$ 149 bio. (national and international spending from 2009 to 2015). This is supposed to increase the percentage of R&D for 'diseases which disproportionately affect developing countries' from currently 3% to then 12%[50]. The 2009 WHA established a WHO Expert Working Group on R&D Financing (EWG)[51]. In 2010 the process of implementing the results of this expert group was stopped, as an impermissible interference of pharmaceutical stakeholders with the final revision of the EWG report had been disclosed. After a new round of discussions at the WHA 2010 a new "Consultative expert working group" presented its report in April 2012. Finally, after two years of further negotiations (at an "Open Ended Meeting on the Follow-up of the Report the CEWG" in November 2012 and at WHA and the EB) there was an agreement to establish a small number of *demonstration projects* to develop medicines in the field of neglected tropical diseases (NTDs), to be financed by a *Pooled Fund for Global Health Research and Development*[52] under the management of the TDR (See above), and a *Global Health Research and Development Observatory*, which will compile data that are available in clinical trial registries, patent libraries, journal databases and existing surveys of R&D expenditure (See: http://www.scidev.net/global/health/opinion/we-can-create-a-sharp-global-picture-of-health-research.html#sthash.oMbwKN1V.dpuf). Furthermore, a "coordination mechanism" is supposed to be established (See: WHO Evaluation of the GSPoA (WHO 2014: results of EB 136). There has, however, been little progress achieved on the R&D Treaty. In the November 2012 "Open-ended meeting" (WHO 2012b), further discussions on that issue were postponed to 2016, but in fact have not been taken up at WHA 69[53].

In the following I analyze the positions of three groups of actors – the positions of important Northern states (HICs), DCs (taking into account regional groupings and, wherever possible, BRICS

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[50] However, a recent study calculates that until 2012 finance for R&D on these diseases does not come even close to the percentage of 12% of total health R&D (See: Røttingen et al. 2013).

[51] In the discourses on WHO issues, acronyms like IGWG, GSPoA, EWG and CEWG (Consultative Expert Working Group) are used although they do not refer to their specific tasks, but only to the type of organization involved.

[52] For discussion on pooled funds in financing health R&D see Grace & Pearson 2011; and Moon 2014.

[53] See KEI (28/05/2016), WHA69: Draft resolution (A69/B/CONF./7) on CEWG follow-up charts course for WHO's work on R&D (http://keionline.org/node/2582).

members) and CSOs/NGOs – in discourses and negotiations at WHA and EB from 2010 (WHA 63 and EB 126) to 2015 (WHA 68 and EB 136) related to agenda items dealing with two key terms ("Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoA)" and "Consultative Expert Working Group" (CEWG). As explained above, CEWG is just a specific element of the GSPoA process. Non-state actors can state their position, if they are invited by the respective chairpersons to do so. Several contributions are available from the Doctors without Borders (Médecins Sans Frontières, MSF), Medicus Mundi International (MMI), Health Accion International (HAI), the International Federation of Medical Students' Associations (IFMSA), the Global Forum for Health Research (GFHR), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Third World Network (TWN) and some others. Most of the statements of non-state actors are made by the group of advocacy CSOs, while, as expected, the few statements of IFPMA and some other non-state actors show considerable differences.

After a first lecture of the official records of the meetings referred to above, there are two issues on which it appears to be useful to focus, as they are contested throughout the five years observed[54]:

(1) The general issue of access to medicine and IPRs, basically accepted to demand forms of de-linking prices of medicines from R&D costs, and in its most far-reaching form the proposal of an R&D treaty to be negotiated through WHO. Such a treaty (introduced by James Law and the cptech group; See above Section 3.4 and fn 42) is supposed to formulate binding obligations to delink R&D costs of medicines from prices for consumers with a focus on diseases which primarily affect developing countries. It was an option formulated in the GSPoA, introduced in the CIPIH (CIPIH/WHO 2006:90) but never seriously considered by most HICs. Though in a rather trimmed-down version, the proposal by WHO to establish a Global Health Research and Development Observatory can be seen at least as a step to improve the informational basis for further steps (Adam et al. 2015).

[54] The decision to establish a "Global Health Research and Development Observatory" organized by WHO elicited a number of queries concerning among other aspects the link between the national level of information provision and the WHO level, and the criteria of information processing, which are considered important for the usefulness of the observatory.

(2) *Mobilization of resources to finance research ("demonstration projects" to start with; pooled funding) in the GSPoA process:* This has been conceived as a general goal to be attained through large voluntary contributions (from public or private sources), which is primarily an obligation for the wealthier member states that ideally should be institutionally monitored through GSPoA – in reality the ability of WHO to impact the mobilization of funds in the proposed dimension is quite low[55] and severe doubts have been voiced about the approach WHO is pursuing with these demonstration projects[56].

The identification of positions on these issues will be at the core of analyzing WHA and EB summary records. Both issues are related to the liberal content and the level of international authority of WHO preferred by the respective actors. However, because of the focus of WHO governance on decisions by consensus, it is not always easy to clearly distinguish positions. Furthermore during negotiations, positions are naturally moving. I will rather take account of their statements in the particular meeting of the EB and the WHA and give an overview of group positions in Table 3. Some other issues appeared from which the establishment of a "Global Health Research and Development Observatory" is the most important, as it appears as a (at least temporary) substitute to an R&D treaty.

I will screen all contributions to discussions recorded under the two key terms (with the exception of those from WHO officials and those obviously not related to GSPoA/CEWG content) and will follow up the positions of different groups of countries/actors in the course of the moving focuses of debates at the WHO governing bodies between 2010 and 2015. While Tables 1 and 2 will summarize information on the degree of involvement of countries and regional groupings in these debates, Table 3 will give an overview on positions related to the main

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[55] Commitments to the Pooled Fund have so far been relatively low. "The total estimated need for the observatory and the demonstration projects is US$85 million and the current gap is over US$76 million, according to WHO. The full amount does not need to be find (sic!) right away, and donor momentum is gaining, WHO Assistant Director General Marie-Paule Kieny told Intellectual Property Watch." (Intellectual Property Watch 2015). Taking into account that the costs of developing a new drug is estimated at a high three-digit amount of million US$, the estimated need for demonstration projects obviously is not set at a very high level.

[56] In an article in Nature, Mary Moran (2014) argues that non-profit, publically financed projects are not suitable to develop R&D models "designed to break commercial patents and profits", but are just competing with other, much better financed projects financed by government and philanthropic grants. But see also the critical comments to this article published in the same issue, which among other aspects refer to the opportunity to test open knowledge approaches to R&D.

aspects of the Foci (1) and (2). I will also refer to other documents, in particular around the *Open Ended Meeting* in 2012 on the Follow-up of the CEWG report, which forms part of the WHO governance process.

IV.3 Results of the analysis of statements at WHA/EB meetings

3.1 Frequency of statements by countries and country groups

I start the presentation of the empirical results by looking at the frequency of statements by countries and country groups. Following the WHA and EB summary records during the period mentioned (2010-2014) there were 246 statements by Member States and 32 by non-state actors. Table 1 gives the list of those countries with the largest number of statements, table 2 offers an overview of the regional distribution of contributions:

Table 1: No. of statements by members

# statements	Member state
15	Switzerland
14	*Brazil*
13	USA
10	*China*
9	Argentina Bolivia Japan Thailand
8	Mexico
..7	Canada Ecuador *South Africa*
6	*India* Norway Paraguay
...	...
..2	*Russia* (and 12 others)

Table 2: No. of statements be regions

Regions	# statements
South & Central America	62
North America (incl. Mexico)	28
European Union	19
Other European (incl. Russia)	26
Africa	37
West-Asia	20
South and SE Asia	26
East Asia (incl. Japan, Australia)	28

The number of statements made by Member States can be seen as a rough indicator of the engagement of the respective countries with the issue of the GSPoA. The reasons for this engagement can be expected to be quite diverse, assuming that there are vested interests among the main home countries of the large TNPCs to uphold the basic framework conditions for their operations, but also urgent needs among low-income countries to improve research on and access to treatment of diseases which primarily affect them, in a sustainable way. This plausible assumption will be checked by screening the content of the statements of the various actor

groups as proposed above. Concerning the particular engagement of Switzerland, we have to take into account not only its role as a leading pharmaceutical producer, but also as the host of the three international organizations most directly involved in matters concerning the international regulation of intellectual property rights and thus also in negotiations concerning the framework of health R&D: WHO, WTO and WIPO (See for the intersections between public health, intellectual property and trade: WHO, WIPO & WTO 2013).

Tables 1 and 2 give evidence to the large differences in the BRICS countries' involvement in the issues discussed here: While Brazil has been commenting on nearly every point in the discussions on the GSPoA and the implementation proposals by the EWG and the CEWG, South Africa and India show a limited engagement (more focused on specific issues within this field), Russia is hardly participating at all. The high involvement of nearly all South American[57] countries is particularly striking; nearly 25% of all statements were made by this group of member states, well-coordinated by meetings of UNASUR (Unión de Naciones Suramericanas). While also many African states made their statements in the WHA/EB discussions, their comments do not reflect the coordination of a strongly dedicated regional power.

3.2 Statements by states and NStAs in the EB and WHA meetings from 2010 to 2015

There is a World Health Assembly each year in May and two meetings every year of the Executive Board in January (preparing the contents of the following WHA) and in May immediately after the WHA (resuming the results of the WHA and preparing work for the coming year). They are continuously numbered starting with the foundation of WHO in 1948 (in 2010: WHA 63; EB 126 und 127[58]). My analysis includes the Open Ended Meeting in 2012 on the Follow-up of the CEWG report[59]. The column headings refer to the most important issues discussed during the six years

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[57] Among Latin American countries, there are few statements from outside South America, i.e. only from Panama and Cuba.

[58] I will use these short versions for the official designations: WHA 63 for "63rd World Health Assembly" and correspondingly EB 126 for "Executive Board, 126th Session" etc.

[59] This report (WHO 2012a) focuses on monitoring R&D resource flows (pushing the idea of a "global observatory for health R&D), coordination of health R&D (leading to the proposition of "pooled funding" as a mechanism for managed coordination) and financing mechanisms, introducing the TDR as a successful funding model with totally voluntary contributions. For the WHO report on the meeting, see WHO 2012b.

covered and introduced in Sections 4.2, they also include statements on the role of WHO and organizational matters related to GSPoA, such as establishing the EWG, CEWG and the demands for an Intergovernmental Working Group instead, which would have enhanced the status of this the CEWG and strengthened the role of member states as against experts and CSO representatives. Since the EB meeting in May 2013 and in particular during 2015,[60] the discussion on the form of evaluation and eventual prolongation of the GSPoA, which had been enacted as a "medium strategic plan for the period of 2008-2015", occupied a growing space.

The cells of table 3 contain (if necessary) a specification of the issue treated at the meeting concerned (in black letters; "+" means in support, "-" against) and the basic statements of member states or regional groupings and non-state-actors made (in red letters). "Generally accepted" means that statements from all groups basically accepted the proposals made. For the Open-ended Meeting, there are no records of statements available; therefore, I only refer to the main content of the draft resolution produced at this meeting (WHO 2012b, Annex), which is important for the following meetings of the EB and the WHA. The entries show the turn of the discourse since 2013 from more conflicting issues (binding R&D treaty, general funding) towards specific proposals which are rather uncontroversial (demonstration projects; pooled funding, global health and development observatory), while only CSOs and DCs (related to longer-term perspectives of GSPoA) continue to argue for more far-reaching goals. There is also an interesting differentiation to be observed between demands for a binding R&D treaty and the "de-linking" goal.

Based on this overview I will analyze in the following sections the positions of non-state actors and rising powers (see Section 4.4) and the impact on the authority of WHO (see Section 4.5), which will also take into account a review of other published statements –in particular concerning actors which have few opportunities to contribute to WHA/EB discourses (mostly CSOs) or by institutions, which will give detailed analyses on the issues concerned (mostly from the US or the UK) and supplementary insights into the discourses and negotiation strategies and on alliances between different types of actor.

[60] Information on the WHA 68 (May 2015) is based on Global Health Watch (2015) as the official records were not available on the WHO website at the time of writing this paper.

Issues / Meeting	A2M/IPs in general	Binding R&D-Treaty	De-linking medical prices from R&D costs	Demonstration projects	Funding/finance in general	Pooled funding model	Global health research and dev. observatory	Role of WHO/status of working groups
EB 126 (2010)	Lack of~ in EWG: 9/10 DC (Ind/Br)& 2 CSO; EWG+: 3/5 HIC& 1 other NStA				Insufficient ref. to funding: 9/10 DC (Ind/Br)& 2 CSO			Too much responsibility to WHO in EWG: US
WHA 63 (2010)	EWG-: 1 CSO EWG+: 3 other NStA							IGWG+: UNASUR, Br/Ind/Indon. IGWG-: 10 DC (R/ Ch) & HIC
EB 128 (2011)								CEWG comp.+: 3 HIC & 9DC; comp-: Br/UNASUR/Th/Bang/
EB 130 (2012)			UNASUR/Ind/Bol		Funding local R&D capacities: Sen/Bur/Moz			Changing mandate of WHA+: Sw; -: Br/Bol/Ecu
WHA 65 (2012)	Not enough incentives to DC R&D: Ch	+:Ken/UNASUR/ 3 CSO -: De (EU)/ No	Ken		Funding local R&D capacities: Aus/Can/Jap/Mon/US/other DCs Local effect.: IFPMA			WHO should play leading role; strengthen South-South coop.: Ch (ref. to BRICS). Open-ended meeting on CEWG: Sw

Op.-end. meeting on CEWG (2012)		-: Draft res.	+: Draft res.		Draft res.	Draft res.	Draft res.	New op.end.meeting before May 2016: Draft res.
EB 132 (2013)		+: Sey (Afro)/ Indon		Generally accepted	Funding mechanism for demo.projs.: Generally accepted		Generally accepted	Reopening draft res. on CEWG: +: 9/13 DCs; -: Mex/Th/SA/Ch; all (12) HICs;
WHA 66 (2013)		Ind/Ch/4 CSOs	Ind/Ch/US (Res.draft)/IFPMA UNASUR		US (Res.draft)/ IFPMA			Op.end. meeting at the earliest possible date (US, Res. draft)
EB 133 (2013)								GSPoA-evaluation: stressing comprehensiveness: Br, SA, Ch
EB 134 (2014)		3 CSOs	3 CSOs	Critique of selection: Arg/Bol		Financially unstable: 3 CSOs	Generally accepted	
WHA 67 (2014)				Critique of selection: Ind	Vol. Fund not sufficient for sustainable financing: 3 CSOs	Pooled funding (TDR): accepted, but risk with Type I diseases: Bol/SA/ UNASUR	Generally accepted, support from all BRICS countries	

WHA 68 (2015)	GSPoA/IP/TRIPS flexibilities: Mau (Afro); Ind, Indon, Chi; 3 CSOs		Mau (Afro); Ind, Indon, Chi; 3 CSOs		Enhanced funding from WHO core budget: 3 CSOs			GSPoA extended to 2015–22; EVA 2018: generally accepted (incl. UNASUR, Ch, SA)

Table 3: Statements by WHO members and NStAs on GSPoA issues (2010–2015)

Table 3: Sources and list of abbreviations

Sources: WHO (2010–2015); WHO (2012a and b).

Abbreviations (other than those used in the text before)**:**

Text:

A2M: Access to medicines

comp.: composition

demo.projs.: demonstration projects

dev.: development

draft res.: draft resolution

IP=IPRs: Intellectual property rights

Local effect.: local effectiveness ("need for prioritization, effectiveness and sustainability"

Op.end. meeting: open-ended meeting

ref.: reference

res. draft: resolution drafted

Type I diseases: diseases with large numbers of vulnerable people in both rich and poor countries (according to CIPIH).

vol. fund: voluntary fund

Countries and country groups:

Afro: WHO African Group

Arg: Argentina

Aus: Australia

Bang: Bangladesh

Bol: Bolivia

Br: Brazil

Bur: Burundi

Can: Canada

Ch: China

Chi: Chile

Ecu: Ecuador

Ind: India

Indon: Indonesia

Jap: Japan

Ken: Kenya

Mex: Mexico

Mon: Monaco

Moz: Mozambique

SA: South Africa

Sen: Senegal

Sey: Seychelles

Sw: Switzerland

Th: Thailand

UNASUR: Unión de Naciones Suramericanas.

IV.4 Non-State actors and Rising Powers at GSPoA negotiations 2010–2015

Based on the review of WHO records, a number of observations can be made concerning the presumed power shift in international relations as well as the rise of international authority (Section 4.5). These observations point to the difficulties to formulate general hypotheses on the impact of the emergence of rising powers in international politics on the one hand, of non-state actors on the other hand. Primarily, in terms of sectoral politics such as global health, it has to be taken into account that this impact depends to an important degree on the specific character of different international institutions in global politics (in this case the specifics of a UN Specialized Agency such as WHO).

(1) What is contested by Rising Powers and/or Non-State Actors?

Concerning the GSPoA process, there is no direct conflict about the decision-making power of different actors or groups of actors within the WHO – the basic rule of seeking compromise for resolutions and decision has not been put into question. The main problem is to reach "meaningful" decisions, i.e. decisions which are not thwarted by activities in other institutional contexts within GHG (e.g. foundation of the GFATM) or by the impacts of counteracting activities in other policy fields (e.g. TRIPS+ provisions in Free Trade Agreements). There is a tendency in GSPoA (just as with the 3 by 5 initiative; Section 3.6) to develop far-reaching goals without WHO being able to have a significant impact on actors important for goal attainment, as e.g. the mobilization of financial means for the over-all GSPoA and R&D projects on neglected tropical diseases on a really significant scale (See fn. 55) or to attain the support of strong international actors for a binding R&D treaty. This affects the role of WHO as the central authority in international health, i.e. the importance of inter-governmental authority within the policy field of GHG, and indirectly, the "liberal content" of the working of GHG. CSOs do not stop demanding a binding R&D treaty, receiving some support from DCs, in particular Brazil with UNASUR, in the discourse on CEWG (WHA 66) also from India and China, but they are not "relevant" for unanimity in the WHA, as long as member states are ready to postpone their respective concerns.

(2) Continuation of the North–South conflict and neoliberal governmentality

Considering the positions of country groups on the issues negotiated, the old North-South conflict seems to continue in a modified form: Concerning two issues, a rather clear North/South division line can be observed: negotiations on a binding R&D convention and the inter-governmental character of the WHO – most DC governments reject any "upgrading" of NStAs in

WHO institutions because of the influence of TNPCs. Still, there is some room for compromise, as a few general norms on access to medicines are accepted by all members, and, furthermore, DCs have learnt that, by alluding to these norms and by abstaining from positions which are directly challenging the liberal order, they are able to benefit from compromises. HICs do generally accept the need to improve health R&D in the field of diseases that primary affect developing countries which made possible the unanimous acceptance of the GSPoA in 2008. It is also accepted that the IPR system is not producing sufficient incentives that support R&D in this field and does not help to guarantee universal access to essential medicines. But none of these countries support negotiations on a binding convention on Health R&D, which would necessarily challenge at least parts of the TRIPS agreement and of references to IP protection in bi- and multilateral trade agreements. On the other hand, many DCs – South American countries, with UNASUR as their regional organization, and also India, Indonesia, Thailand, Kenya and some others are insisting (until 2013) on the priority of negotiations of a binding treaty on Health Research and Development at WHO. Most statements of developing countries in the WHA/EB discourses demand a strengthening of public responsibility in R&D financing, but they are ready to compromise in order to reap some concrete gains from WHO negotiations. This tendency of dominant actors to propose compromises which recognize problems of the poorer world (without giving up own essentials) on the one hand and of more marginal actors to accept what is attainable in a political arena dominated by neoliberal norms on the other hand, points to the importance of the concept of neoliberal governmentality[61].

(3) We cannot observe clear positions of rising powers

No clear coordination of positions is observable among the rising powers. Though there are annual meetings of the BRICS health ministers, during the five years of WHA and EB meetings only one single statement of the Chinese representative mentions BRICS (WHA 65) and there is one other meeting with similar statements from all BRICS countries, but without explicit reference to BRICS (WHA 67). The Beijing Declaration of the BRICS Health Ministers Meeting in 2011 is close to a WHO consensus statement (Knowledge Ecology International 2011). On many

[61] "Governmentality" refers to disposing of means to define "...'the imbrication [interweaving. W.H.] of men and things', 'men' in their myriad relations with climate, wealth, resources, the territory and so on." (Larner & Walters 2004:3, following Foucault 1991:93). This does not imply an identification with a certain community, but the acceptance of particular norms (such as property rights, rule of law etc.).

issues, representatives from one or the other BRICS country share positions with other DCs. On the other hand, it seems that among emerging powers there is a tendency towards seeing a growing space for private finance (See the Chinese comment on "The Future of Financing WHO"[62], also statements on the pooled funding model within the GSPoA process), but also here a coordinated position of BRICS countries cannot be observed. In IPR issues Brazil is clearly the most active of the BRICS, but within WHO Brazil is mostly coordinating its position with its fellow UNASUR countries. While India at times supports these statements, South Africa plays a very limited role and Russia does not take part in this discourse. South Africa sometimes supports demands of other African countries on the importance of financial and technical assistance, but does not take a leading role like Brazil in the case of UNASUR.

(4) Among non–state actors there is a clear line between advocacy CSOs and business–related NGOs

Among non-state actors there is a clear differentiation between advocacy CSOs (pushing for a strengthening of WHO and inter-governmental authority to counter the liberal dominance in global trade governance) and business-related NGOs such as the IFPMA[63]. It has to be taken into account, however, that "civil society" is not a homogeneous group of actors (See e.g. some faith-based organizations), but that the visible positions of CSO groups depend on historical situations and on political constellations. CSOs like the MSF, MMI and HAI demand a significant increase in reliable international financing and immediate start of negotiations (at least of serious discussions) on a binding medical R&D convention, when they are invited to talk at the WHO governing institutions. Their position is clearly formulated in a "Joint Letter to the 66th World Health Assembly" signed by 45 CSOs who demand that "formal negotiations should begin for a binding global instrument for R&D and innovation for health" of 20 May 2013 (Knowledge Ecology International 2013). In many aspects advocacy CSOs are reliably sharing DC positions,

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[62] "China suggests WHO establish a dedicated financing management unit to raise funds through a unified voice and action, so as to avoid unreasonable internal competition. Meanwhile innovative financing channels should be explored. While avoiding conflict of interests, the Organization should also consider an appropriate portion of donations from companies and NGOs." (http://www.who.int/dg/future_financing/china_20100723.pdf?ua=1)

[63] There are statements of some other NGOs, such as the International Alliance of Patients' Organizations and the Global Forum for Health Research, which can neither be associated with the positions of advocative CSOs nor with those of business associations.

but there is one dividing line, that is the strong defense by DCs of Member State authority in an IGO such as WHO.

(5) Limited impact of CSOs on issues without large public pressure

During GSPoA negotiations, advocative CSOs in general take positions in line with those in the conflict on access to medicines analyzed in the first part of this working paper. In contrast to their role in the access conflict, their impact on the course of the negotiations remained limited. Possibly, their insistence on a binding R&D treaty might help getting this topic back into the center of attention after 2016. Three interrelated reasons seem to be plausible: (a) the GSPoA process takes place in an intergovernmental organization, which defends its legitimacy based on intergovernmentalism against the myriad of non-state and hybrid GHG actors and where decisions are taken by representatives of states, which sometimes speak on behalf of regional groupings, but always on an inter-*governmental* platform, (b) DC governments in particular, though in many issues supported by CSOs, are opposed to a more effective opening of WHO towards NStAs as they are afraid of a stronger influence of TNPCs (See above: Section 2.3), and (c) the issue of GSPoA has never received a strong attention of a larger public through which CSOs could have had a greater impact on the position of national governments – as had happened in the access conflict.

IV.5 The GSPoA and the authority of WHO in the 2010s

I have shown that since the turn of the Millennium, WHO has been trying hard to regain its authority in global health. Due to its focus on intergovernmental agreements and coordination, the GSPoA has been introduced in this contribution as a great opportunity for strengthening the international authority of WHO. The following points indicate why the results have been mixed so far.

(1) Organizational form of WHO: decisions based on consensus, strength of regional organizations within WHO

As explained above, WHO decisions are generally based on consensus. Therefore, divergent positions cannot be observed through voting behavior, but only through statements in the preceding discussions (and certainly in documents produced in other contexts, which, however, frequently are not fully comparable to each other). Here processes of contestation are comparatively clear, but are also blurred by the consensus perspective as a precondition for advancing a certain process (such as the broadly accepted aim of GSPoA of promoting research

and development on neglected diseases). Another important aspect is related to the strength of regional organizations (regional entities within WHO, organizations of regional integration) in WHO negotiations. Before meetings of the WHO governing institutions there are usually consultations among the members of the WHO regions, but also health-related consultations of other regional groupings. UNASUR plays a particularly strong role in this context.

(2) R&D observatory as a compromise product

While the goal of increased financing of R&D for neglected diseases has been a central point of the GSPoA and played an important role during the process analyzed in this paper, the proposal of establishing an R&D observatory came up as a typical compromise product. It could be accepted as an interim goal by member states demanding negotiations on a binding convention (expecting to provide solid information on the inadequacy of the IP system to produce medicines for neglected diseases and universal access to essential medicines as a global public good), but it stopped short of actually entering into such negotiations. As the observatory as such does not infringe TRIPS and the IPR system in general, this proposal was also acceptable for HICs.

(3) WHO, the GSPoA and access to medicines

Thus, the negotiation process at WHO has integrated itself into the multi-faceted support for the norm "universal access to essential medicines" as an element of the right to health, without moving an important step forward towards developing anything close to an international regime on health R&D. This norm constitutes the foundation of the whole GSPoA process; without its general acceptance (consensual approval by WHO Member States in the WHA 2008) such an intensive and long discourse would not have been possible. On the other hand, taking into account the diversity of interests between stakeholders, the chance to develop something like a binding treaty bridging the gap between IPRs and global health needs seems to be scarce. The reference to "TRIPS flexibilities" as a way to react to health emergencies has been broadly accepted in general; but significant conflicts could be observed concerning in particular the range of diseases and medicines to be included, the practices of national patent offices evolving etc. The flexibility of an informal political norm to some degree accepted and internalized by all stakeholders seems to be closer fitting into a world characterized by a globalizing society and a fragmented structure of global governance (Hein & Moon 2013). More research in this field is urgently needed.

(4) The authority of WHO, GHG and the BRICS

Conflicts around the role of the WHO – contestation of its loss of importance in the complex field of global health governance – are closely linked to a twofold process towards *distributed authority.* On the one hand there has been a loss of authority of WHO as a consequence of the proliferation of actors in global health and the rise of GHG, on the other hand there is no doubt that there have been challenges of the political dominance of the most powerful HICs by two groups of actors: non-state actors and transnational public pressure (which is closely related to global governance processes); and a group of rising powers with a growing role in international relations. While the growing role of the BRICS (including some other MICs) is also recognized in the global health discourse (e.g. GHSi 2012; Brown et al. 2013; Huang 2013; Hein & Moon 2013), this case study has shown that this is not clearly mirrored through their engagement in the WHO governing institutions. Brazil and China are among the top contributors to the discourses analyzed, but there is no coherent BRICS position. UNASUR has an aligned position among its member states, which is probably closely related to a strong position of Brazil in matters of GHG (Fraundorfer 2013). For other regions the alignment is not that strong: African members refer in some of their statements to the African Union, in others to the African Group within WHO (basically Sub-Saharan Africa). China and India in some cases refer to the South East Asian group of WHO, but other members of this group do not, in particular Thailand and Indonesia.

In fact, pursuing the issue of GSPoA could be seen as a partially successful strategy of WHO to re-assume its position as the international authority in an important field of global health, since NStAs being institutionally marginalized and member states being eager to avoid paralyzing conflicts. As we have seen, however, consensus has only been achieved at the cost of a reduced public attention and political impact[64]: Despite its original claims, GSPoA has not been able to tackle the great issues of "public health, innovation and intellectual property", but has reached

[64] See e.g. the statement by the CSO Medicus Mundi at the 136th session of the WHO EB (Jan/Febr. 2015): "The strategy was a pioneering attempt by a UN agency to undo a global governance mistake of the '90s, by reclaiming the terrain from the trade agenda and give it back to the 'human rights' agenda... Frankly, the implementation of this strategy is anything but a success story". http://www.ghwatch.org/sites/www.ghwatch.org/files/EB136_MMI-PHM_Statement_105_GSPOA.pdf (05/06/2016). There are similarly critical statements by other CSOs published on the ip-Health/ keionline e-mail-list (MSF: 29.1.2016; Intellectual Property Watch: 9.5.2016, Third World Network: 2.6.2016).

consensus through a strategy of confining itself to some manageable goals to be attained without mobilizing the whole network of GHG.

V. CONCLUSIONS

The paper started with the observation that in the context of post-war embedded liberalism WHO had to take care of international health problems in a double sense – a cooperative and mobility-supporting form of dealing with diseases which could not be controlled at the national level, and aid to help poorer world areas to improve health at home. Hegemony was constituted by a combination of various forms of power: On the one hand, power is conferred by voting-rights. The rule "one country/one vote" is an expression of the concept of formal equality between nation states in international law. On the other hand power is exercised through impact in global affairs (based on economic, political-military, and discursive power). In the early post-war period, voting-power in UN Organizations played a role in the rising East-West-conflict, but rarely led to a coordinated use of voting by DCs.

Neoliberalism prevailed after the crisis of embedded liberalism (or Fordism) in the late 1960s and 1970s, linked to pressures for liberalization to use new economic opportunities (e.g. through new transport and communication technologies). This put in motion a new, more pervasive phase of globalization with many facets, stimulating growth in many regions combined with an increase of inequality and a growing world-wide consciousness of marginalization and misery including new forms of transnational threats. It also implies a greater transnational mobility and influence of NStAs (business as well as CSOs) and the rise of new economic and political powers in world regions beyond Europe and North America (for a summary: Hein 2016).

WHO as a welfare-oriented organization characterized by low liberal content, dealing with technical cooperation and political activities (Stephen & Zürn 2014), which counteract impacts of a liberal economic system, became one of the foremost examples of the crisis of multilaterals in the neoliberal era. Developing countries, led by three of today's rising powers (Brazil, China and India), had a strong position within WHO due to voting-rules and the strong regionalization. The seriousness of global health problems, in particular linked to the HIV/AIDS pandemic, was increasingly realized by the G7/8 and the US in particular. They denied WHO a budgetary boost which would have allowed the health organization to strengthen its authority according to the challenges faced, but supported the foundation of new institutions in global health (GFATM, other public private partnerships), and strengthened the role of philanthropic foundations in international health financing. The role of WHO as "the directing and co-ordinating authority on

international health work" was contested. This was a significant step in the rise of Global Health Governance, as other organizations became increasingly the focus of alignment or contestation by civil society organizations, sidelining WHO in many issues of global health– and thus reducing its authority.

The two conflicts analyzed in this paper, demonstrate processes of contestation in GHG and around the attempts of WHO to regain authority. At first glance, the successfully concluded negotiations of the FCTC (2003) and the new IHR (2005) seemed to re-assert the position of WHO in global health, but finally the impact on WHO authority remained at best mixed. While in the case of the FCTC, which had been supported by all relevant global health actors, WHO could effectively work as a coordinating authority, the role of WHO in the management of IHR remains contested. In 2003, the achievement of stopping the SARS epidemic by using instruments of the new IHR (which at that time were still being negotiated) had been hailed, but the declaration of a health emergency in the case of the so-called swine-flu (H1N1) in 2009, was widely criticized as basically benefitting the pharmaceutical industry (because of the unnecessary stockpiling of anti-viral medicines). In the case of the West-African Ebola epidemics (2014-2016), WHO was heavily accused of reacting too late, but also of not having sufficiently pushed for securing the "core capacity requirements for surveillance and response" (Annex 1 of the IHR) in poor developing countries (Hein 2016a) – largely because of a lack of resources. This again points to the dependence of the WHO's operational capacity on other GHG actors.

In section 3 the positions and strategies of non-state actors in the conflict on IPRs and health are analyzed as well as those of rising powers, of which India and Brazil both strongly – though from different national perspectives – allied themselves with the access movement and played important roles for the development of affordable HIV drugs and treatment in DCs. In an important field of international health, WHO seemed to lose completely its "directing and coordinating authority" to a seemingly chaotic system of GHG. Successes were attributed to other actors of GHG, in particular to a strong campaign of CSOs and to opportunities of treatment opened-up by two rising powers.

In the policy field of "public health, innovation and intellectual property" the attempts to re-assert WHO's authority as an intergovernmental actor resulted in the process leading to the GSPoA. WHO tried to capitalize on this apparent normative rapprochement by pursuing the access discourse. The implementation, however, led to the re-appearance of the fundamental conflicts on basic rules (convention on medical R&D) and finance. Section 4 analyses the positions and strategies of main actors concerning these issues. Among non-state actors we can

observe a fight for the role of WHO as an independent coordinator and broker in GHG. As could have been expected, there is a fundamental conflict between explicitly health/human rights oriented, political CSOs on the one hand and the lobbying role of TNPCs and their business associations on the other. GHG has been politicized from the beginning, as the conflict between these two groups of non-state actors on medical innovation and access to medicines has always been critical. For WHO, it has been difficult to hold the balance, as its epistemic role was closely related to links to R&D in the pharmaceutical industry (which then use the lobbying opportunities), while its coordination and health promotion role was mostly supported by CSOs.

The analysis of the debates on the GSPoA and the CEWG do not point to a unified strategy among the BRICS and rising powers in general to strengthen their position among WHO member states – with the exception of Brazil which strongly engages in activities in these fields, including its role as a regional power through UNASUR. There are other Southern states, which continuously play an important role in global health affairs, in particular Thailand and Kenya, but it seems that the positions among the emerging countries differ considerably[65]. DCs in general, however, are afraid of easing the way to more influence of pharmaceutical companies, if the role of NStAs in WHO is strengthened, and therefore they insist in fully upholding the intergovernmental character of the organization.

Contested World Orders? Observations in this chapter on the role of NStAs in global health affirm that *international relations* have been transformed into *global politics*, in as far as it is characterized by interactions (and alliances) between very different types of actors – states, inter-national and transnational organizations of a diverse character, and a variety of non-state actors. The conflict on access to medicines and the experience of global governance processes have led to a more subtle and flexible approach by actors to pursue their goals.

The dominant liberal world order needs institutions which on the one hand promote norms that support some basic social rights as a foundation of a broader popular acceptance of this order. The norm of "universal access to essential medicines" now is accepted also by those actors who admit that the liberal order they support contributes to causing the problem to be addressed. Thus, dominant actors from the North are ready to make compromises not with respect to the

[65] See Harmer & Buse 2014; Gautier et. al 2014 on the current role of the BRICS countries in global health and on future perspectives.

core rules of the liberal order but with respect to certain limited, though possibly marginally effective approaches to reduce the gap between the current access situation and the norm. For authoritative rules and agreements, intergovernmental organizations have to be addressed; conflictive positions are defined by non-state actors seeking support for binding regulations from states/governments. The latter align themselves with NStAs according to their specific interests, but they do no longer fight for dominating WHO because they know that important developments in global health occur outside WHO. The role of rising powers is ambiguous as on the one hand they are supporting the welfare-orientation of WHO in fighting "diseases of the poor", but on the other hand they want to strengthen their position in the global economy (including the pharmaceutical industry) and know that WHO only plays a secondary role.

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